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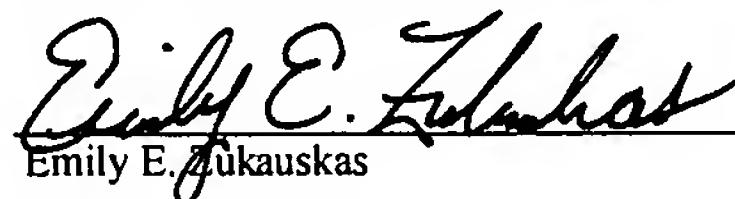
DOCKET NO.: G0762.70006US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Schlegel et al.  
Serial No.: 10/565,021  
Confirmation No.: 9002  
Filed: January 17, 2006  
For: DIAGNOSIS AND TREATMENT OF CERVICAL CANCER  
Examiner: Not Yet Assigned  
Art Unit: Not Yet Assigned

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 10<sup>th</sup> day of August, 2006.

  
Emily E. Zukauskas

MAIL STOP AMENDMENT  
Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- First Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:

  
Patricia Granahan, Sc.D., Reg. No.: 32,227  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: G0762.70006US01

Date: August 16 2006

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Emily E. Zukauskas

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MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

FIRST STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office action on the merits in the above-identified case.

No fee or certification is required.

**PART II: Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

**PART III: Remarks**

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Serial No.: 10/565,021  
Conf. No.: 9002

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Art Unit: Not Yet Assigned

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

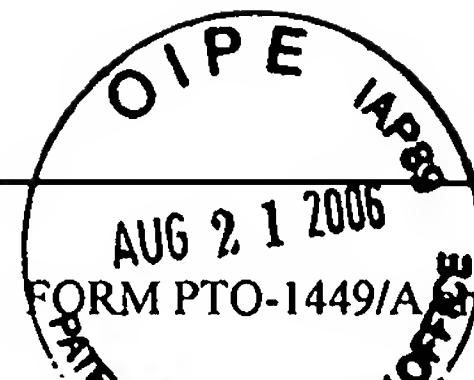
An early and favorable action is hereby requested.

Respectfully submitted,

By:

  
Patricia Granahan, Sc.D., Reg. No. 32,227  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: G0762.70006US01  
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**xNDDx**



FORM PTO-1449/A and B (modified PTO/SB/08)			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			
Sheet	1	of	3

APPLICATION NO.: 10/565,021	ATTY. DOCKET NO.: G0762.70006US01
FILING DATE: January 17, 2006	CONFIRMATION NO.: 9002
APPLICANT: Schlegel et al.	
GROUP ART UNIT: Not Yet Assigned	EXAMINER: Not Yet Assigned

#### U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	5,989,807		West et al.	11-23-1999

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B1	WO	99/29890	A2	Digene Corporation	06-17-1996	
	B2	WO	02/08764	A1	Medical Research Council	01-31-2002	
	B3	WO	02/078695	A1	Board of Regents, The University of Texas System	10-10-2002	
	B4	International Search Report and Written Opinion. International Application: PCT/US2004/023014. Mailing date: April 14, 2005.					
	B5	International Preliminary Report on Patentability. International Application: PCT/US2004/023014. Mailing date: February 2, 2006.					

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	ANDERSON et al., Telomerase activation in cervical cancer. Am J Pathol. 1997 Jul;151(1):25-31.	
	C2	BAEGE et al., Cervical epithelial cells transduced with the papillomavirus E6/E7 oncogenes maintain stable levels of oncoprotein expression but exhibit progressive, major increases in hTERT gene expression and telomerase activity. Am J Pathol. 2002 Apr;160(4):1251-7.	
	C3	BAEGE et al., IGFBP-3, a marker of cellular senescence, is overexpressed in human papillomavirus-immortalized cervical cells and enhances IGF-1-induced mitogenesis. J Virol. 2004 Jun;78(11):5720-7.	
	C4	BAXTER et al., Binding proteins for the insulin-like growth factors: structure, regulation and function. Prog Growth Factor Res. 1989;1(1):49-68.	

EXAMINER:

DATE CONSIDERED:

<sup>#</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**INFORMATION DISCLOSURE  
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Sheet

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of

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C5	BAXTER et al., Insulin-like growth factor (IGF)-binding proteins: interactions with IGFs and intrinsic bioactivities. Am J Physiol Endocrinol Metab. 2000 Jun;278(6):E967-76.	
C6	BAXTER et al., Signalling pathways involved in antiproliferative effects of IGFBP-3: a review. Mol Pathol. 2001 Jun;54(3):145-8.	
C7	BERGER et al., Insulin-like growth factor-binding protein 3 expression increases during immortalization of cervical keratinocytes by human papillomavirus type 16 E6 and E7 proteins. Am J Pathol. 2002 Aug;161(2):603-10.	
C8	BLACKWOOD et al., Max: a helix-loop-helix zipper protein that forms a sequence-specific DNA-binding complex with Myc. Science. 1991 Mar 8;251(4998):1211-7.	
C9	HENRIKSSON et al., Phosphorylation sites mapping in the N-terminal domain of c-myc modulate its transforming potential. Oncogene. 1993 Dec;8(12):3199-209.	
C10	IMURA et al., Beta-catenin expression as a prognostic indicator in cervical adenocarcinoma. Int J Mol Med. 2001 Oct;8(4):353-8.	
C11	KANG et al., Diagnose kit detect cervix cancer. Database WPI, XP002305239 & KR 2002 012 838. Biogrand Co Ltd. February 20, 2002. Abstract.	
C12	KELLEY et al., Insulin-like growth factor-binding proteins (IGFBPs) and their regulatory dynamics. Int J Biochem Cell Biol. 1996 Jun;28(6):619-37.	
C13	KIM et al., Specific association of human telomerase activity with immortal cells and cancer. Science. 1994 Dec 23;266(5193):2011-5.	
C14	LLOYD et al., Demonstration of an epitope of the transferrin receptor in human cervical epithelium—a potentially useful cell marker. J Clin Pathol. 1984 Feb;37(2):131-5.	
C15	MEYERSON et al., hEST2, the putative human telomerase catalytic subunit gene, is up-regulated in tumor cells and during immortalization. Cell. 1997 Aug 22;90(4):785-95.	
C16	PEIFER et al., Beta-catenin as oncogene: the smoking gun. Science. 1997 Mar 21;275(5307):1752-3.	
C17	RAMAKRISHNAN et al., Expression profile of the putative catalytic subunit of the telomerase gene. Cancer Res. 1998 Feb 15;58(4):622-5.	
C18	RUBINFELD et al., Stabilization of beta-catenin by genetic defects in melanoma cell lines. Science. 1997 Mar 21;275(5307):1790-2.	
C19	SHINOHARA et al., Cytoplasmic/nuclear expression without mutation of exon 3 of the beta-catenin gene is frequent in the development of the neoplasm of the uterine cervix. Gynecol Oncol. 2001 Sep;82(3):450-5.	
C20	TAKAKURA et al., Expression of human telomerase subunits and correlation with telomerase activity in cervical cancer. Cancer Res. 1998 Apr 1;58(7):1558-61.	
C21	THOMAS et al., Human papillomavirus oncoproteins E6 and E7 independently abrogate the mitotic spindle checkpoint. J Virol. 1998 Feb;72(2):1131-7.	
C22	ÜREN et al., Activation of the canonical Wnt pathway during genital keratinocyte transformation: a model for cervical cancer progression. Cancer Res. 2005 Jul 15;65(14):6199-206.	
C23	VELDMAN et al., Transcriptional activation of the telomerase hTERT gene by human papillomavirus type 16 E6 oncoprotein. J Virol. 2001 May;75(9):4467-72.	

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DATE CONSIDERED:

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C24	VELDMAN et al., Human papillomavirus E6 and Myc proteins associate in vivo and bind to and cooperatively activate the telomerase reverse transcriptase promoter. Proc Natl Acad Sci U S A. 2003 Jul 8;100(14):8211-6.	
C25	YATABE et al., 2-5A antisense therapy directed against human telomerase RNA inhibits telomerase activity and induces apoptosis without telomere impairment in cervical cancer cells. Cancer Gene Ther. 2002 Jul;9(7):624-30.	
C26	YUAN et al., Simian virus 40 small tumor antigen activates AKT and telomerase and induces anchorage-independent growth of human epithelial cells. J Virol. 2002 Nov;76(21):10685-91.	

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_, filed \_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

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